UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

RONALD KRICK and MARY KRICK, Plaintiffs, v. MEDTRONIC, INC., Defendant.	)	Case No. 1:18-cv-176

NOTICE OF REMOVAL

PLEASE TAKE NOTICE THAT, pursuant to 28 U.S.C §§ 1441, 1446, Defendant Medtronic, Inc. ("Medtronic") hereby removes this action, *Ronald Krick and Mary Krick v. Medtronic, Inc.*, Case No. 18-00225-NI, Circuit Court for Kent County to the United States District Court for the Western District of Michigan. In support, Medtronic states as follows:

Background Facts

1. On January 5, 2018, Plaintiffs filed an action against Medtronic in the Circuit Court for Kent County, Michigan. The case was docketed under Case No. 18-00225-NO. Service was obtained on Medtronic via CT Corporation System on January 22, 2018. A copy of the entire state court file is attached as Exhibit A, and includes all pleadings served or filed in this action as of the date of this notice, including the Complaint and Summons.

2. The Complaint alleges that Plaintiff Ronald Krick's Medtronic pacemaker was a proximate cause of his "syncopal episode" leading to a car accident and subsequent injuries sustained by both Plaintiffs, Ronald Krick and Mary Krick. Exhibit A, Complaint ¶ 56. The Complaint also alleges that Medtronic's representative breached his/her duty of ordinary care by "failing to properly administer the testing of the pacemaker and/or by failing to properly interpret

the results" of Plaintiff Ronald Krick's pacemaker when the Medtronic representative tested and evaluated the performance of Plaintiff Ronald Krick's pacemaker prior to the car accident. Exhibit A, Complaint ¶¶ 52, 54.

3. The alleged device is a Medtronic Pacemaker Model 5524M CapSure SP. *See* Exhibit A, Complaint, Exhibit 1 (Implanted Device Identification Card). Plaintiffs assert causes of action for Negligence (Count I) and Breach of Implied Warranty (Count II).

4. Under 28 U.S.C. § 1446(b), this Notice of Removal must be filed within 30 days of service of the Complaint and Summons upon Medtronic. Because Defendants are filing this Notice on February 20, 2018, removal is timely.

5. The time for Medtronic to answer, move, or otherwise plead with respect to the Complaint has not yet expired. *See* Exhibit A.

6. Concurrent with the filing of this Notice, Medtronic is serving the Notice on Plaintiffs' counsel and filing a Notice of Filing of Notice of Removal and a copy of this Notice with the Clerk of the Circuit Court for Kent County. A copy of the Notice of Filing of Notice of Removal being filed in the Circuit Court of Kent County (excluding the exhibit) is attached as Exhibit B.

7. Venue is proper in this Court pursuant to 28 U.S.C. §§ 102(a)(1) and 1441(a), because the U.S. District Court for the Western District of Michigan is the federal judicial district embracing the Circuit Court of Kent County, Michigan, where this action was originally filed.

8. By filing a Notice of Removal in this matter, Medtronic does not waive any right to assert any defense and/or objection to which the Defendant may be entitled.

Diversity Jurisdiction

9. Subject matter jurisdiction, particularly federal diversity jurisdiction, is proper

under 28 U.S.C. § 1332. Diversity jurisdiction exists where (1) the amount in controversy exceeds $75,000, exclusive of interest and costs, and (2) the suit is between citizens of different states. *Ljuljdjuraj v. State Farm Mut. Auto. Ins. Co.*, 774 F.3d 908, 910 (6th Cir. 2014).

10. Complete diversity exists between the parties to this action. Defendant Medtronic, Inc. is a corporation "incorporated under the laws of Minnesota and maintaining its principal place of business in Minnesota." *See Branson v. Medtronic, Inc.*, No. 5:06-cv-332, 2007 WL 170094 at * 4 (M.D. Fla. Jan. 18, 2007) (denying plaintiff's motion to remand following removal by Medtronic on the ground that Medtronic's principal place of business is in Minnesota). Thus, Medtronic is a citizen of Minnesota for purposes of federal diversity jurisdiction. Plaintiffs are citizens of Michigan. In the Complaint, Plaintiffs do not deny that they "live[] in Kent County." Exhibit A, Complaint ¶¶ 1, 2.

11. It is facially apparent that Plaintiffs' claimed damages, and thus the amount in controversy, exceed $75,000. The Complaint alleges that the malfunction of the pacemaker caused Mr. Krick's syncopal episode which led to a car crash where both Plaintiffs suffered injuries. Complaint ¶¶ 56, 62. The Complaint alleges Plaintiff Mary Krick "may not be able to walk again without assistance" due to the injuries she sustained in the car crash that Plaintiffs allege was caused by Plaintiff Ronald Krick's pacemaker. Exhibit A, Complaint ¶ 49. In addition to this permanent injury, Plaintiffs allege numerous surgeries have resulted from this car accident, namely Ronald Krick's RV lead revision and Mary Krick's multiple surgeries related to her left femur fracture, as well as physical therapy and rehabilitation to address her injuries. Exhibit A, Complaint ¶ 36, 46, 47, 48. Thus, there are sufficient facts to reasonably support an amount in controversy over $75,000. *See Naji v. Lincoln*, 665 Fed. App'x 397, 401–02 (6th Cir. 2016) (finding allegations of "permanent" damages satisfied jurisdictional amount-in-controversy

requirement); *Basicomputer Corp. v. Scott*, 973 F.2d 507, 510 (6th Cir. 1992) (affirming the district court's finding that it had diversity jurisdiction over the dispute because there was no legal certainty that plaintiff's claims were worth less than the amount in controversy); *Beeching v. Showboat Hotel, Casino, Country Club and Bowling Center*, No. 1:91-cv-127, 1991 WL 526303 at *1 (W.D. Mich. Apr. 1, 1991) (holding it is sufficient to effect removal where plaintiffs' claims of permanent injuries giving rise to present and future damages support a claim that the amount in controversy exceeds the threshold).

12. The fact that Plaintiffs allege only that the amount in controversy exceeds $25,000 is not determinative of whether or not the amount in controversy exceeds the statutory threshold of $75,000. *Beeching*, 1991 WL 526303 at *2 (W.D. Mich. Apr. 1, 1991) (holding that plaintiff's complaint cannot be conclusive on the issue of the amount in controversy because Michigan law restricts plaintiffs to pleading only that the amount in controversy is in excess of $10,000,[1] and deciding the amount in controversy based on the complaint would make removal by a defendant impossible in Michigan); *see* M.C.R. 2.111.

13. If the Court believes that additional facts are needed to establish the jurisdictional amount, Medtronic respectfully seeks leave to take jurisdictional discovery from the Plaintiffs. *See LGT Enterprises, LLC v. Hoffman*, No. 1:08-cv-578, 2008 WL 5744180 at *5 (W.D. Mich. Dec. 17, 2008) (granting jurisdictional discovery where additional facts were necessary to establish personal jurisdiction).

14. Accordingly, this Court has federal diversity jurisdiction under 28 U.S.C. § 1332, and this case is removable under 28 U.S.C. § 1441.

[1] The current version of M.C.R. 2.111 restricts plaintiffs to pleading only that the amount in controversy is in excess of $25,000—the same amount alleged by Plaintiffs in this case.

Federal-Question Jurisdiction

15. In the alternative, Medtronic seeks to remove this matter based on federal-question jurisdiction. Under 28 U.S.C. § 1331, the district courts "have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States."

16. Plaintiffs' case stems from the alleged malfunctioning of Plaintiff's Medtronic Pacemaker Model 5524M CapSure SP, an FDA-approved prescription device that treats heart conditions. Plaintiffs allege that Ronald Krick's syncopal episode was "due to malfunction of his right ventricular lead of his previously placed pacemaker." Exhibit A, Complaint ¶ 41.

17. Federal regulation of medical devices is governed by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c, *et seq*. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). The MDA establishes three classes of increasingly stringent federal oversight. *Id*. at 316–17.

18. Class III includes devices that "support[] or sustain[] human life" or "present[] a potential unreasonable risk of illness or injury." 21 U.S.C. §360c(a)(1)(C)(ii). Class III devices "receiv[e] the most federal oversight" and must withstand "a rigorous regime of premarket approval" before they may be brought to market. *Riegel*, 552 U.S. at 317.

19. The Pacemaker at issue in the Complaint is a Class III medical device, the design, manufacturing method, and labeling of which were specifically approved by the Food and Drug Administration ("FDA") pursuant to the agency's Premarket Approval ("PMA") process. *See* U.S. Food & Drug Admin., Premarket Approval Database, Medtronic Capture SP Model 5524M Pacing

Leads, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P850089S035.[2]

20. Section 360k(a) of the MDA expressly preempts any state-law claim that would impose a requirement that is "different from, or in addition to" those imposed by the FDA. 21 U.S.C. § 360k(a); *see Riegel*, 552 U.S. at 321–28. Through this provision, Congress expressly preempted state-law tort claims challenging the design, manufacture, or labeling of a medical device previously approved by the FDA via the PMA process.

21. This preemption provision has a narrow exception for claims that "'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330. To be "parallel," a state-law requirement must be "identical" to a federal requirement. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996).

22. Plaintiffs allege that Medtronic impliedly warranted that the pacemaker implanted in Ronald Krick was reasonably fit for its intended use, and that Medtronic breached the implied warranty because the pacemaker was not reasonably fit for its intended use. Exhibit A, Complaint ¶¶ 59, 60. Thus, Plaintiffs' claim challenges the safety and effectiveness of a device subject to pervasive federal regulation and administrative oversight.

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[2] This web page is part of the FDA's public database of premarket approvals, which is accessible at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. This Court may take judicial notice of the fact of the Pacemaker's premarket approval because the FDA's public website is a database maintained by the FDA in the normal course of its business and reflects final agency action. *See* Fed. R. Evid. 201; *Jones v. City of Cincinnati,* 521 F.3d 555, 562 (6th Cir. 2008) (observing that a "court may consider public records" under judicial notice); *see also Thorn v. Medtronic Sofamor Danek, USA, Inc.*, 81 F. Supp. 3d 619, 622–23 (W.D. Mich. 2015) (noting that publicly available information on the FDA website may be judicially noticed) (citing *In re Epogen *623 & Aranesp Off–Label Mktg. & Sales Practices Litig.,* 590 F. Supp. 2d 1282, 1286 (C.D. Cal. 2008)); *Albrecht v. Fort Dodge Animal Health, Inc.*, No. 12-cv-11429, 2013 WL 823325, at *3 (E.D. Mich. Mar. 6, 2013) ("[T]he Court may take judicial notice of [FDA] action under Fed. R. Evid. 201."); *Aaron. v. Medtronic, Inc.*, No. 13-cv-202, 2016 WL 5242957, at *16 (S.D. Ohio Sept. 22, 2016) ("This Court may take judicial notice of Infuse's receipt of PMA from the FDA, including the device's FDA-mandated warning label which includes the warranty disclaimers.").

23. A claim may arise under federal law in either of two ways. In many cases, "federal-question jurisdiction is invoked . . . by plaintiffs pleading a cause of action created by federal law." *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 312 (2005). In other cases, although the plaintiff's cause of action is nominally created by state law, "federal-question jurisdiction will lie over state-law claims that implicate significant federal issues." *Id.* This second form of federal-question jurisdiction "captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Id.*

24. Because Plaintiffs' warranty claim will require the Court to second-guess the design, manufacturing, and programming of this Class III medical device, a resolution necessarily will "implicate significant federal issues" and "turn on substantial questions of federal law." *Grable*, 545 U.S. at 312; *see Arrington v. Medtronic, Inc.*, 130 F. Supp. 3d 1150, 1159–60 (W.D. Kent. 2014) ("Because the Infuse® is a Class III, PMA device under the MDA, the Court finds that Plaintiffs' claims against Defendants' alleged misuse and improper promotion of the Infuse® appropriately elicits an analysis under the substantial-federal-question doctrine. Plaintiffs' claims undoubtedly require this Court to examine federal law, and, even more specifically, examine federal requirements imposed by the FDA through the premarket approval process."); *accord H.R. ex rel. Reuter v. Medtronic, Inc.*, 996 F. Supp. 2d 671, 677-81 (S.D. Ohio 2014).

25. Accordingly, this Court has federal question jurisdiction under 28 U.S.C. § 1331, and this case is removable under 28 U.S.C. § 1441.

WHEREFORE, Defendant respectfully requests that this action be removed as set forth above.

Dated: February 20, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Albert M. Bower, hereby certify that on February 20, 2018 the foregoing document was filed via the Court's CM/ECF system, and also sent via U.S. mail to counsel for Plaintiffs:

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